

## REMARKS

Claims 1, 3-4, 6-28, 30-31, 33-36, and 46-57 are pending in the present Application, with claims 10-27 and 46-54 withdrawn as directed to nonelected subject matter.

Withdrawn claims 10-27 and 46-54 are cancelled, claims 1, 3, and 30 are amended, and new dependent claims 58 and 59 are added, leaving Claims 1, 3-4, 6-9, 28, 30-31, 33-36, and 55-59 for consideration upon entry of the present Amendment.

Reconsideration and allowance of the claims are respectfully requested in view of the above amendments and the following remarks.

### Claim Amendments

Claim 1 is amended to correct a typographic error noted by the Examiner. Claims 3 and 30 are amended to correct their dependency.

Support for new claims 58 and 59 are found in the specification at least at p. 4, lines 2-6.

### Claim Objections

Claim 1 is objected to for the informality of the recitation of “in the form a tingling sensation” and an apparently missing “of” after “form”.

Claim 1 is amended to include the word “of”.

Claims 3 and 30 are objected to for the informality of depending from cancelled claims. Claims 3 and 30 are amended to correct the dependency of each claim.

Applicant requests withdrawal of the objections to claims 1, 3, and 30.

### Claim Rejections Under 35 U.S.C. § 103(a)

Claims 1, 3-4, 6-9, 28, 30-31, 33-36, and 55-57 stand rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over Carpenter (US 5637344; hereinafter “Carpenter”) in view of the combination of Raymont (AU 71907/96 A; hereinafter “Raymont”) and Seang (WO 94/05260; hereinafter “Seang”). Applicants respectfully traverse this rejection.

Independent claim 1 is directed to a hard boiled candy composition comprising: (a) a confectionery base comprised of a mixture of at least one sugar and at least one carbohydrate bulking agent which is kept in an amorphous or glassy condition; (b) at least one botanical

selected from the group consisting of Echinacea, Siberian Ginseng, Ginko Biloba, Kola Nut, Goldenseal, Golo Kola, Schizandra, Elderberry, St. Johns Wort, Valerian and Ephedra, and combinations thereof, each having an unpleasant mouthfeel in the form of a tingling sensation or astringency characteristic of said group of botanicals; and, (c) an amount of from about 0.5% to about 5.0% by weight of said hard boiled candy composition of an unpleasant mouthfeel suppressing agent for suppressing the tingling sensation or astringency characteristic of said group of botanicals, said unpleasant mouthfeel suppressing agent consisting of one or more partially hydrogenated vegetable oils or saturated fats, said amount being effective to suppress said unpleasant mouthfeel of said group of botanicals. Claims 3-4, 6-9 and 56 depend directly or indirectly from claim 1.

Independent claim 55 is directed to a hard boiled candy composition consisting essentially of: (a) a confectionery base comprised of a mixture of at least one sugar and at least one carbohydrate bulking agent which is kept in an amorphous or glassy condition; (b) at least one botanical selected from the group consisting of Echinacea, Siberian Ginseng, Ginkgo Biloba, Kola Nut, Goldenseal, Golo Kola, Schizandra, Elderberry, St. Johns Wort, Valerian and Ephedra, and combinations thereof, each having an unpleasant mouthfeel in the form of a tingling sensation or astringency characteristic of said group of botanicals; and (c) an unpleasant mouthfeel suppressing agent for suppressing the tingling sensation or astringency characteristic of said group of botanicals, said unpleasant mouthfeel suppressing agent consisting of from about 0.5% to about 5.0% by weight of said hard boiled candy composition of one or more partially hydrogenated vegetable oils or saturated fats, said amount being effective to suppress said unpleasant mouthfeel of said group of botanicals.

Independent claim 28 is directed to a method for suppressing the unpleasant mouthfeel of a hard boiled candy composition which contains a botanical having an unpleasant mouthfeel, which comprises: (a) providing a confectionery base comprised of a mixture of at least one sugar and at least one carbohydrate bulking agent which is kept in an amorphous or glassy condition and a botanical selected from the group consisting of Echinacea, Siberian Ginseng, Ginkgo Biloba, Kola Nut, Goldenseal, Golo Kola, Schizandra, Elderberry, St. Johns Wort, Valerian and Ephedra, and combinations thereof, each having an unpleasant mouthfeel in the form of a tingling sensation or astringency characteristic of said group of botanicals, and (b) adding thereto from

about 0.5% to about 5.0% by weight of said hard boiled candy composition of an unpleasant mouthfeel suppressing agent for suppressing the tingling sensation or astringency characteristic of said group of botanicals, said unpleasant mouthfeel suppressing agent consisting of one or more partially hydrogenated vegetable oils or saturated fats said amount being effective to suppress said unpleasant mouthfeel of said group of botanicals. Claims 30-31, 33-36, and 57 depend directly or indirectly from claim 28.

“A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *KSR Int’l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007). To find obviousness, the Examiner must “identify a reason that would have prompted a person of ordinary skill in the art in the relevant field to combine the elements in the way the claimed new invention does.” *Id.*

With regard to the hard boiled candy composition of claims 1, 3-4, 6-9, and 55-56, Carpenter is generally directed to an amorphous crystalline chocolate flavored hard candy confection using air-jet milled cocoa powder with particles less than 15  $\mu$  having generally rounded edges. (Abstract) Carpenter teaches that one example of a hard candy chocolate product sold in Japan with a surface dusted with cocoa powder had a rough, coarse, sandy surface and that such characteristics are not acceptable for hard candy. (col. 1, lines 20-26) Carpenter discloses that use of air-jet-milled cocoa powders impart characteristic chocolate flavor to the hard candy without the “sandpaper texture”. (col. 9, lines 20-23) Carpenter further discloses that oil, when present in his chocolate-flavored hard candy, facilitates mixing the air-jet milled cocoa powder and the amorphous candy mass by facilitating dispersion of the air-jet milled cocoa powder and adds perceived richness to the final product and improves the texture thereof. (col. 6, lines 58-65) Carpenter discloses that the oil can be either a dairy-based oil or a vegetable oil. (col. 6, lines 60-61) Carpenter discloses that when the optional oil is added, “it is present in sufficient amounts to facilitate mixing of the air-jet milled cocoa powder with the amorphous candy mass” (col. 7, lines 37-40) and that the weight ratio of air-jet-milled cocoa powder to the oil ranges from about 1:3 to about 100:1, and more preferably 0.67:1 to 1.5:1. (col. 7, lines 42-45) For stamped products, Carpenter states that the preferred amount of oil in the hard candy should preferably be kept at less than 5% by weight, and for molded products, then the amount of oil is preferably greater than 3% by weight. (col. 8, last line bridging to col. 9, line 6)

However, Carpenter does not disclose, or even suggest, a hard boiled candy composition comprising at least one botanical selected from the group consisting of Echinacea, Siberian Ginseng, Ginko Biloba, Kola Nut, Goldenseal, Golo Kola, Schizandra, Elderberry, St. Johns Wort, Valerian and Ephedra, and combinations thereof, each having an unpleasant mouthfeel in the form of a tingling sensation or astringency characteristic of said group of botanicals; or an amount of from about 0.5% to about 5.0% by weight of said hard boiled candy composition of an unpleasant mouthfeel suppressing agent for suppressing the tingling sensation or astringency characteristic of said group of botanicals, said unpleasant mouthfeel suppressing agent consisting of one or more partially hydrogenated vegetable oils or saturated fats, said amount being effective to suppress said unpleasant mouthfeel of said group of botanicals as required in independent claims 1 and 55.

Raymont is generally directed to a therapeutic compositions comprising one or more vitamins and/or provitamins, one or more amino acid metal chelates, Echinacea extract, Ginkgo biloba extract, one or more antioxidants, together with a pharmaceutically acceptable carrier vehicle. (Abstract) Raymont teaches that his particular combination of active ingredients has a significant synergistic effect, with a therapeutic effect greater than the additive effect of the various components. (p. 2, para. 2, lines 7-10) Raymont teaches that his composition may be formulated as tablets, capsules, lozenges, emulsions, solutions, and suspensions (p. 3, lines 30-31) , but does not provide any explicit examples of the composition in any formulation other than a tablet. (pp. 7-8) In Raymont's composition, the Echinacea extract can be present at 1.5-4 w/w% and the Ginkgo biloba can be present at 0.08-4 w/w%. (p. 6, lines 26-27)

However, Raymont does not teach or suggest inclusion of an unpleasant mouthfeel suppressing agent for suppressing the tingling sensation or astringency characteristic of said group of botanicals, said unpleasant mouthfeel suppressing agent consisting of from about 0.5% to about 5.0% by weight of said hard boiled candy composition of one or more partially hydrogenated vegetable oils or saturated fats, said amount being effective to suppress said unpleasant mouthfeel of said group of botanicals as required in claims 1 and 55.

Seang discloses that his invention relates to compositions comprising a drug having its taste masked by a lipid coating contained within an aqueous polymer system for oral administration. (p. 1, lines 5-8) Seang teaches that a means of preparing drugs with an

unpalatable bitter taste for oral administration is in a granule-lipid format which are suspended in an aqueous solution immediately prior to oral administration and that in this manner, the drug is not dissolved in the mouth of the patient, but passes on to the gastrointestinal tract where it is dissolved by stomach fluids. (p. 1, lines 11-25)

Seang discloses a method of producing a stable drug composition masking a drug flavor in which a particulate drug is mixed with a lipid below the temperature of significant drug-degradation, and to this drug-lipid mixture is added an emulsifier, a polymer solution and a dilution solution to form the stable taste-masked drug composition. (p. 2, line 29 to p. 3, line 2) Seang discloses an alternative method in which a mixture of a lipid and an emulsifier are heated until brought into the molten state, the molten mixture is cooled to a temperature below the temperature of significant drug-degradation and then admixed with the particulate drug to form a flavor masked drug/lipid dispersion, to which a polymer solution is added to form a concentrated drug composition, and finally a dilution solution is added to form the final drug composition. (p. 3, lines 3-15) Note that the drug compositions of Seang are dispersions (p. 3, lines 17-18), rather than a solid composition as in the claimed invention. Seang teaches the drug is selected from cimetidine, ranitidine, ibuprofen, acetaminophen, and erythromycin. (p. 3, lines 15-17)

Seang discloses that the lipid can be a hydrogenated or partially hydrogenate oil such as cottonseed oil, castrol oil, and coconut oil. (p. 6, lines 8-9) Seang teaches that the amount of lipid ranges from 25-200% of the amount of drug employed, but is preferably in a lipid:drug ratio of 1:1, and the maximum amount of lipid added to a 10 cc solution of the drug composition is about 800 mg. (p. 8, lines 8-12)

However, Seang does not teach or suggest inclusion in a hard boiled candy composition of an unpleasant mouthfeel suppressing agent for suppressing the tingling sensation or astringency characteristic of said group of botanicals, said unpleasant mouthfeel suppressing agent consisting of from about 0.5% to about 5.0% by weight of said hard boiled candy composition of one or more partially hydrogenated vegetable oils or saturated fats, said amount being effective to suppress said unpleasant mouthfeel of said group of botanicals as required in claims 1 and 55.

Thus applicants contend that all elements of the compositions of independent claims 1 and 55 are not disclosed or suggested by the cited combination of references.

Further, Applicants contend that the Examiner's rationale for combining the references is technically faulty. The Examiner states that since Seang teaches that lipids (oils and fats) were known for masking the bitter taste (i.e., unpleasant mouthfeel), that it would have been obvious to one of ordinary skill in the art at the time of the invention that the partially hydrogenated oils or saturated fats in Applicants range will suppress the unpleasant mouthfeel of the botanical in the invention of claims 1 and 55.

Applicants contend this rationale for modifying Carpenter with Seang to obtain the invention of claims 1 and 55 is faulty because Seang is directed to dosage forms that are liquid dispersions of a particular selection of bitter drugs (cimetidine, ranitidine, ibuprofen, acetaminophen, or erythromycin) and methods of preparing such dispersions. The claimed compositions are solid hard boiled candy compositions. The examiner has provided no evidentiary support for the proposition that a method of taste-masking a particular selection of drugs in a liquid dispersion format would have motivated an artisan to include an unpleasant mouthfeel suppressing agent for suppressing the tingling sensation or astringency characteristic of a botanical selected from Echinacea, Siberian Ginseng, Ginkgo Biloba, Kola Nut, Goldenseal, Golo Kola, Schizandra, Elderberry, St. Johns Wort, Valerian and Ephedra, and combinations thereof, said unpleasant mouthfeel suppressing agent consisting of from about 0.5% to about 5.0% by weight of said hard boiled candy composition of one or more partially hydrogenated vegetable oils or saturated fats, said amount being effective to suppress said unpleasant mouthfeel of said group of botanicals as required in claims 1 and 55.

For all the above reasons, claims 1, 3-4, 6-9, and 55-56 and new claims 58-59 are not obvious over the combination of Carpenter, Raymont, and Seang.

Even if a prima facie case of obviousness were conceded, which it is not, it is respectfully submitted that applicant's invention is not obvious because the particular combination of claimed elements results in unexpectedly beneficial properties. An applicant can rebut a prima facie case of obviousness by presenting comparative test data showing that the claimed invention possesses unexpectedly improved properties or properties that the prior art does not have. *In re Dillon*, 919 F.2d 688, 692-93, 16 U.S.P.Q.2d 1987, 1901 (Fed. Cir. 1990).

Applicants show in Example 1 (pp. 8-10) and Example 2 (p. 10) of the instant specification an unexpectedly large suppression of the tingling sensation of a representative

botanical, Echinacea, alone or in combination with Siberian Ginseng, by addition of a partially hydrogenated vegetable oil or saturated fat at about 0.5% to about 5.0% by weight of the hard boiled candy compositions. See Table A (p. 8) showing percent reduction in the tingling mouthfeel of greater than 57.5 % and p. 10, lines 14-17. As the claimed compositions show unexpectedly superior reduction in the unpleasant tingling sensation, Applicants contend the hard boiled candy compositions of claims 1, 3-4, 6-9, 55-56, and new claims 58-59 are not obvious over the combination of Carpenter, Raymont, and Seang.

Reconsideration and withdrawal of the rejection of claims 1, 3-4, 6-9, and 55-56 are requested.

With respect to method claims 28, 30-31, 33-36, and 57, Carpenter does not disclose or suggest adding to a confectionary base, comprised of a mixture of at least one sugar and at least one carbohydrate bulking agent which is kept in an amorphous or glassy condition and a botanical, one or more partially hydrogenated vegetable oils or saturated fats in an amount effective to suppress said unpleasant mouthfeel in the form of a tingling sensation or astringency characteristic of the botanical in the hard boiled candy composition. In contrast, Carpenter teaches that the oil is added to the air-jet milled cocoa powder prior to mixing with the amorphous candy mass in order to facilitate mixing of the cocoa powder with the amorphous candy mass. (col. 7, lines 37-42 and Example II (col. 9, line 65 – col. 10, line 13))

With respect to independent method claim 28, Raymont does not disclose or suggest adding to a confectionary base, comprised of a mixture of at least one sugar and at least one carbohydrate bulking agent which is kept in an amorphous or glassy condition and a botanical, one or more partially hydrogenated vegetable oils or saturated fats in an amount effective to suppress said unpleasant mouthfeel in the form of a tingling sensation or astringency characteristic of the botanical in the hard boiled candy composition. Raymont only provides amounts and ranges of ingredients for his compositions. However, Raymont does not provide any details as to how to make his compositions.

With respect to independent method claim 28, Seang discloses a method of producing a stable drug composition, in the form of a liquid dispersion and masking a drug flavor, in which a particulate drug is mixed with a lipid below the temperature of significant drug-degradation, and

to this drug-lipid mixture is added an emulsifier, a polymer solution and a dilution solution to form the stable taste-masked drug composition. (p. 2, line 29 to p. 3, line 2) Seang discloses an alternative method in which a mixture of a lipid and an emulsifier are heated until brought into the molten state, the molten mixture is cooled to a temperature below the temperature of significant drug-degradation and then admixed with the particulate drug to form a flavor masked drug/lipid dispersion, to which a polymer solution is added to form a concentrated drug composition, and finally a dilution solution is added to form the final drug composition. (p. 3, lines 3-15)

However, Seang does not disclose or suggest adding to a confectionary base, comprised of a mixture of at least one sugar and at least one carbohydrate bulking agent which is kept in an amorphous or glassy condition and a botanical, one or more partially hydrogenated vegetable oils or saturated fats in an amount effective to suppress said unpleasant mouthfeel in the form of a tingling sensation or astringency characteristic of the botanical in the hard boiled candy composition.

As all elements of independent method claim 28 are not disclosed or suggested by the combination of Carpenter, Raymont, and Seang, claims 28, 30-31, 33-36, and 57 are not obvious over the combination of references.

Further, as discussed above with respect to the hard boiled candy compositions, such compositions made by the claimed method are shown to have an unexpectedly superior reduction in the unpleasant tingling sensation associated with compositions lacking the added unpleasant mouthfeel suppressing agent. As the method produces unexpectedly superior hard boiled candy compositions, method claims 28, 30-31, 33-36, and 57 are not obvious over the combination of Carpenter, Raymont, and Seang.

For all the above reasons, reconsideration and withdrawal of the rejection of claims 28, 30-31, 33-36, and 57 over the combination of Carpenter, Raymont, and Seang are requested.



It is believed that the foregoing amendments and remarks fully comply with the Office Action and that the claims herein should now be allowable to Applicants. Accordingly, reconsideration and allowance are requested.

If there are any additional charges with respect to this Amendment or otherwise, please charge them to Deposit Account No. 06-1130.

Respectfully submitted,

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